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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,686	07/28/2003	Gabriele Lualdi	APV31644	4591
7590 05/04/2005				
STEVENS, DAVIS, MILLER & MOSHER, LLP Suite 850 1615 L Street, N.W. Washington, DC 20036			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/627,686	LUALDI ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 15, 16, 18, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 14, 17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/18/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: Figs. 1,2.

Species II: Fig. 3.

Species III: angled couplings (page 9 of spec.)- claims 15,25.

Species IV: offset couplings (page 9 of spec.)- claims 16,26.

Species V: single coupling with pin means (page 9 of spec.)- claim 18.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Anthony Venturino on 4/29/05 a provisional election was made with traverse to prosecute the invention of Species I, claims 1-10,13,14,17-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11,12,15,16,18,25,26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10,24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "said flange-type insert comprises a second portion" in line 2 of the claim. The claims from which claim 8 depends never recited "a first portion" and thus is indefinite. Additionally, it is not clear how "a second coupling of said flange-type insert with an upper end of said pin means" occurs when no first coupling has been recited. It appears the claim should depend from claim 4.

Claim 9 recites the limitation "said second coupling" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. It appears the claim should depend from claim 8. Claim 24 depends from claim 9.

Claim 10 recites the limitation "the upper zone" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,7,8,13,17,21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ficat et al. (3064645). Fig. 1 shows a femoral prosthesis with "substantially cylindrical" pin means 1 with a conical shape and a smaller end and a

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larger end where it is coupled to the head. Fig. 3 shows a removable femoral head 11 and coupling means 8 that is capable of being inserted into a seating of the femoral head via the upward projecting cylinder portion of the coupling means. Figs. 5-7 illustrate that the coupling means 8 comprise a flange 10. Fig. 8 illustrates that the coupling means 8 is connected to the pin means via threaded portion 9. Fig. 13 shows coupling means able to engage the top portion of the femur. It can be construed that the flanged insert is coupled eccentrically with the femoral head and the insert is fully capable of being cemented on the top of the femur. Ficat discloses inserting the stem or pin in the femur (Fig. 8) and then has the coupling means and head applied. It is inherent that the head is applied last since the apparatus is designed as removable and is implanted according to the patient's specifications or anatomical requirements, col. 2, lines 15-20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5,6,9 (as best understood),14,19,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ficat et al. '645 in view of Townley (6096084). Ficat et al. is explained supra. Ficat also shows (Fig. 13) the first coupling being coaxial with the second coupling. However, Ficat et al. fail to disclose the coupling is of a conical type and that a seating is used to surround a top portion of the femur or the femoral head of

a different material than the pin means. Townley shows (Fig. 8) a conical type coupling and the prosthesis surrounding the top portion of the femur. Townley teaches that the head and stem are made of different materials for structural purposes, col. 3, lines 35-39, col. 5, lines 53-63, col. 6, lines 53-61. It would have been obvious to one of ordinary skill in the art to use a conical coupling and also surround the femur as taught by Townley in the prosthetic femoral device of Ficat such that it is secured more and will not unattach since it surrounds the femur. A modification in the coupling means involves only routine skill in the art. It would have been obvious to one of ordinary skill in the art to use two different materials for the components such as ceramic for the head as taught by Townley with the device of Ficat such that it improves the articulation surface.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ficat et al. '645 in view of Leonard et al. (FR 2773469). Ficat et al. is explained supra.

However, Ficat et al. fail to disclose the upper part of the housing in the flanged insert clamped to the pin means by a screw. Leonard et al. teach (Fig. 2) a prosthesis with a screw **16** to be placed in a housing **14** of a flanged insert **9** that is clamped to pin means **1**. It would have been obvious to one of ordinary skill in the art to modify the coupling of the components and use a screw as taught by Leonard et al. in the prosthesis of Ficat et al. since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ficat et al. '645 in view of Pappas et al. (5030234). Ficat et al. is explained supra. Ficat does disclose the head is made of a cobalt alloy, col. 5, line 49. However, Ficat et al. fail to

disclose the pin means and the flanged insert being made of titanium. Pappas et al. teach that stems made of titanium are more flexible than cobalt alloys, col. 6, lines 53-61. It would have been obvious to one of ordinary skill in the art to modify the pin means and insert to be of titanium as taught by Pappas et al. in the prosthesis of Ficat et al. since it will provide a more flexible stem to insert in the bone, but provides a strong articulating head.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino